

REMARKS

I. Amendments

By this amendment, claims 12, 16 and 17 have been amended and claims 18-20 have been cancelled.

This amendment adds no new matter to the specification. Support for the amendment may be found in the specification as originally filed.

No amendment of inventorship is necessitated by this amendment.

II. Discussion of the Rejection under 35 U.S.C. Sec. 112, First Paragraph

Claims 12-14 and 16-20 have been rejected under 35 U.S.C. Sec. 112, first paragraph, for allegedly failing to comply with the written description requirement. Applicants respectfully traverse the rejection.

The Examiner believes that the Experimental Example 2 (wherein the tyrosine kinase inhibitor is PD153035) is not sufficiently representative of the genus of tyrosine kinase inhibitors recited in independent claims 12, 16 and 17 so as to comply with the written description requirement. Applicants disagree.

To show the Examiner that a variety of tyrosine kinase inhibitors are useful in the presently claimed methods, additional experimental evidence with different tyrosine kinase inhibitors is provided in the accompanying Naito Declaration. The Declaration shows that the various tyrosine kinase inhibitors inhibit cell growth, with at least double the effect of using cyproterone acetate alone. In attached Appendix A, the structures of the various inhibitors are provided for the Examiner's convenience.

Applicants do not believe that the aspects of their invention as set forth in independent method claims 12, 16 and 17 as amended are lacking compliance with the written description requirement. Claims 13 and 14 depend upon claim 12. Applicants assert that the more specific dependent claims are also in compliance with the written description requirement. Claims 18-20 have been cancelled.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, first paragraph rejection.

III. Discussion of the Rejection under 35 U.S.C. Sec. 112, First Paragraph

Claims 12-20 have been rejected under 35 U.S.C. Sec. 112, first paragraph, as allegedly lacking enablement. Applicants respectfully traverse the rejection.

The present inventors have found that the expression of a growth factor receptor (e.g., EGF receptor) in prostatic cancer cells is unexpectedly increased by administration of a hormonal agent for the purpose of treatment of a hormone-dependent cancer (prostatic cancer) (see Experimental Example 1 and Figure 1). For a person skilled in the art, it is well-known that a non-hormone dependent cancer (prostatic cancer) is caused by an increase in expression of a growth factor receptor in prostatic cancer cells.

The present inventors have also found that the growth of prostatic cancer cells caused by increased expression of the growth factor receptor due to administration of the hormonal agent can be effectively suppressed by administration of a tyrosine kinase inhibitor of a cell growth factor receptor possessing tyrosine kinase activity (Experimental Example 2 and Figure 2).

Therefore, the aspects of the present invention as set forth in independent method claims 12, 16 and 17 as amended are adequately enabled. Claims 13, 14 and 15 depend upon claim 12. Applicants assert that the more specific dependent claims are also in adequately enabled. Claims 18-20 have been cancelled.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, first paragraph rejection.

IV. Discussion of the Rejection under 35 U.S.C. Sec. 102(b)

Claims 12-17 have been rejected under 35 U.S.C. Sec. 102(b) as allegedly being anticipated by WO 98/32423. Applicants respectfully traverse the rejection.

Claims 18-20 have not been subjected to rejection over the cited reference. Applicants have incorporated the subject matter of these claims into their related independent claims 12, 16 and 17. Therefore, Applicants assert that the aspects of the present invention as set forth in independent method claims 12, 16 and 17 as amended are not anticipated by the cited reference. Claims 13, 14 and 15 depend upon claim 12. Applicants assert that the more specific dependent claims are also not anticipated by the cited reference for the reason provided above.

Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 102(b) rejection.

V. Discussion of the Rejection under 35 U.S.C. Sec. 103(a)

Claims 12-17 have been rejected under 35 U.S.C. Sec. 103(a) as allegedly unpatentable over Schally *et al.*, Pinski *et al.*, or U.S. Patent No. 6,211,215 in view of WO 98/32423.

Applicants respectfully traverse the rejection.

Claims 18-20 have not been subjected to rejection over any of the cited references either individually or in combination. Applicants have incorporated the subject matter of these claims into their related independent claims 12, 16 and 17. Therefore, Applicants assert that the aspects of the present invention as set forth in independent method claims 12, 16 and 17 as amended are not rendered obvious by the teachings of any of the cited references or combinations thereof. Claims 13, 14 and 15 depend upon claim 12. Applicants assert that the more specific dependent claims are also not rendered obvious by the teachings of any of the cited references or combinations thereof for the reason provided above.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103(a) rejection.

VI. Discussion of Obviousness-Type Double Patenting Rejection

Claims 12-17 have been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 5-30 of U.S. Patent No. 6,716,863. Applicants respectfully traverse the rejection.

Claims 18-20 have not been subjected to the obviousness-type double patenting rejection over the cited reference. Applicants have incorporated the subject matter of these claims into their related independent claims 12, 16 and 17. Therefore, Applicants assert that the aspects of the present invention as set forth in independent method claims 12, 16 and 17 as amended are not rendered unpatentable for obviousness-type double patenting over the cited reference. Claims 13, 14 and 15 depend upon claim 12. Applicants assert that the more specific dependent claims are also not rendered unpatentable for obviousness-type double patenting over the cited reference for the reason provided above.

Therefore Applicants respectfully request withdrawal of the obviousness-type double patenting rejection over the '863 reference.

VII. Discussion of the Provisional Obviousness-Type Double Patenting Rejection

Claims 12-17 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 9-39 of co-pending U.S. Patent Application Serial No. 10/620,706. Applicants respectfully traverse the rejection.

Claims 18-20 have not been subjected to the obviousness-type double patenting rejection over the cited co-pending application. Applicants have incorporated the subject matter of these claims into their related independent claims 12, 16 and 17. Therefore, Applicants assert that the aspects of the present invention as set forth in independent method claims 12, 16 and 17 as amended are not rendered unpatentable for obviousness-type double patenting over the cited co-pending application. Claims 13, 14 and 15 depend upon claim 12. Applicants assert that the more specific dependent claims are also not rendered unpatentable for obviousness-type double patenting over the cited co-pending application for the reason provided above.

Therefore Applicants respectfully request withdrawal of the provisional obviousness-type double patenting rejection.

VIII. Discussion of the Objection to Claims 12-20

Claims 12-20 have been objected to for allegedly being drawn in the alternative to a species of the invention that does not share the same special technical feature of the elected species of the invention. Applicants respectfully traverse the rejection.

Applicants believe that the Examiner has misread their claims, which are directed to methods of treating with (i) a hormonal agent *and* cyproterone acetate in combination with (ii) a tyrosine kinase inhibitor. The “or” of component (i) in independent claims 12, 16 and 17 refers to salts of the hormonal agent. It does not make cyproterone acetate an optional component.

Therefore Applicants respectfully request withdrawal of the objection to the claims.

IX. Conclusion

Reconsideration of the pending claims as amended and allowance is requested.

Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, the Examiner is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

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